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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,829	11/29/2001	Donald T. Shannon	VAS-5041CIP2	5289

7590  
Edwards Lifesciences LLC  
Law Dept.  
One Edwards Way  
Irvine, CA 92614

09/24/2007

EXAMINER
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PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

MAIL DATE	DELIVERY MODE
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09/24/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

09/997,829

Applicant(s)

SHANNON, DONALD T.

Examiner

Brian E Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 103-119 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 103-119 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

## DETAILED ACTION

### ***Response to Board Decision***

Prosecution on the merits of this application is reopened on claims 103-119 and considered unpatentable for the reasons indicated below: it is the Examiner's position that these claims are obvious in view of the newly cited reference(s). Rejections based on the new prior art follow.

### ***Priority***

The Examiner notes the Applicant's cancellation of claim to priority to prior applications that was filed on 11/29/04.

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 08/675644, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The prior application did not disclose a coating with a therapeutic agent. Thus the effective date is 11/29/01.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 103,104,106,108-110,113-117 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barclay et al. (2002/77693) in view of Myers et al. (5700285). Barclay et al. show (Fig. 1E) a stent having a tubular form with a plurality of openings in the wall of the device. Barclay et al. also disclose (Fig. 5F) that the stent comprises a therapeutic substance **147** disposed on the wall **139** surface of the stent and an outer layer **141A** of PTFE with a polymer coating **143**. Barclay discloses the PTFE is sintered, paragraph 41. With respect to claim 104, the polymer coating is bioerodible, paragraph 42. Regarding claim 106, the therapeutic substance can be paclitaxel, paragraph 44. Regarding claim 110, it can be seen a linear connector 112 joins the elements that form the spirals. With respect to claims 115,116 the stent can be self-expanding and shape memory material, paragraph 3. Regarding claim 117, Figs. 5B,5C,7E all illustrate the stent can have graft material on its inner surface to form a "base graft". It can be construed that the stent length can remain "substantially constant" when expanded since the disclosure of Applicant's invention provides no basis as to how much of a deviation is permitted from a length being constant by the word "substantially" preceding constant. However, Barclay et al. fail to disclose the PTFE material is tape. Myers

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teaches to place an outer tubular layer of at least one overlapping PTFE tape layer about the stent surface, col. 3, lines 56,57, col. 5, lines 35,44-49 and to sinter the tape, col. 5, lines 59-62. Myers also teaches that the tape applied to form a graft layer and sintered to the stent such that it produces a thinner profile, col. 2, lines 21-24,32,33,col. 3, lines 5-8. It would have been obvious to one of ordinary skill in the art to use tape as taught by Myers et al. with the coil stent of Barclay et al. such that it provides an easy way to apply the PTFE material to the stent since it is a coil stent and Myers discloses the tape can be wrapped along a tubular stent. Additionally, it provides a thinner profile once it is adhered to the stent by heating as opposed to an extruded layer placed on a stent. Regarding claim 113, Myers discloses a thickness for the tape less than 0.015 inches, col. 8, lines 3,4.

Claims 105,107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barclay et al. 2002/77693 in view of Myers et al. '285 as applied to claim 103 above, and further in view of Choi et al. (4131648). Barclay et al. in view of Myers is explained above. However, Barclay as modified by Myers fail to disclose the polymer erodes at about 2 $\mu$ /hr in aqueous environment with a pH of 6-8 or that the polymer is dioxycarbon moiety. Choi et al. teach a polymer coating that is erodible and comprises a therapeutic agent, col. 2, lines 64-68. Choi additionally teaches that polymer is useful in aqueous environments, col. 28, lines 50-57,67,68. Choi teaches (col. 1) the dioxycarbon moiety. It would have been obvious to one of ordinary skill in the art to substitute absorbable polymers and use the dioxycarbon moiety of Choi for the polymer of Barclay as modified

by Myers to provide a sustained release using a known polymer. Interchanging polymers would only involve routine skill in the art.

Claim 111 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barclay et al. 2002/77693 in view of Myers et al. '285 as applied to claim 103 above, and further in view of Wijay (6053940). Barclay et al. in view of Myers is explained above.

However, Barclay as modified by Myers fail to disclose the undulating elements of the spiral as being zigzags. Wijay teaches (Figs. 1,10) zig zag structures in stent devices are advantageous in that the V-shape peaks or valleys hold their deformed position much better and do not recoil, col. 5, lines 55-59. It would have been obvious to one of ordinary skill in the art to form a zig zag pattern as taught by Wijay in the stent of Barclay et al. as modified by Myers et al. such that it reduces the risk of the stent recoiling in the patient and not supporting the vessel wall as intended.

Claim 112 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barclay et al. 2002/77693 in view of Myers et al. '285 as applied to claim 103 above, and further in view of Becker (6117165). Barclay et al. in view of Myers is explained above.

However, Barclay as modified by Myers fail to disclose the undulating spiral with sinusoidal elements. Becker teaches a stent having a plurality of undulating elements with a sinusoidal pattern, Fig. 5. Becker also teaches (Fig. 5) that the pattern can be used in a helical fashion to form the tubular stent. Becker additionally teaches the sinusoidal elements in a spiral or helix stent allow the stent to more uniformly expand, col. 6, lines 23-33. It would have been obvious to one of ordinary skill in the art to use sinusoidal elements in a spiral or helical stent pattern as taught by Becker in the stent of

Barclay et al. as modified by Myers et al. in order to provide the maximum support to the vessel and increasing the effective range of coverage of the stent.

Claims 118,119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barclay et al. 2002/77693 in view of Myers et al. '285 as applied to claim 117 above, and further in view of Banas et al. (5749880). Barclay et al. in view of Myers is explained above. However, Barclay as modified by Myers fail to use PTFE particles for bonding the tubular inner and outer layers. Banas et al teach an aqueous polymer solution of PTFE between the inner graft and outer graft layer to bond the layers, col. 10, lines 4-8. Banas also teaches the outer tubular layer is heated to bond to the base, col. 20, lines 41-45. It would have been obvious to one of ordinary skill in the art to substitute the adhesive material and use PTFE particles (in solution) as taught by Banas with the stent of Barclay et al. as modified by Myers et al. in order to provide a good seal so the graft layers do not separate in the vessel. Using like materials enhances the bond as opposed to the use of an adhesive material that is dissimilar to the PTFE to bond with.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (8:30-5pm).

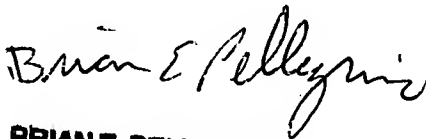
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone

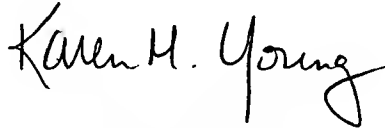
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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700, AU 3738

  
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